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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,039

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Mikhail Vladimirovich Kutushov

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PAULEY PETERSEN & ERICKSON
2800 WEST HIGGINS ROAD
SUITE 365
HOFFMAN ESTATES, IL 60195

EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,039	Applicant(s) KUTUSHOV, MIKHAIL VLADIMIROVICH	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/7/08, 10/22/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-16, 21-25 and 27-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-16, 21-25 and 27-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-5, 7-16, 24, 25, 27-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,980,479 to Kutushov in view of US 5,934,888 to Marka et al.

In the specification and figures, Kutushov '479 discloses the apparatus substantially as claimed by applicant. With regard to claim 38, Kutushov '479 discloses a system for correcting a biological fluid such as blood comprising various channels 42, 52, 84 and valves 61, 78, 80, 84, 88, 99A, that are connected to one another. The apparatus comprises a fluid inlet 44 and fluid outlet 46, a vessel 50 containing a biocompatible suspension of a magneto-conductive material with a sorbent, mixing chamber 66 for mixing the magnetic sorbent with blood, a chamber 70 for precipitation of the magnetic sorbent with magnets 72, 74, and a filter 82 connected to the outlet of the precipitation chamber (see FIG 2 and accompanying text).

Kutushov fails to disclose that the chambers have variable capacities with a hard lid, and flexible, corrugated interchamber partitions. With regard to applicant's claim drawn to a rotating hinged lid, applicant claims such a structure in the alternative. The Examiner has chosen the single fixed lid to reject the claims. Bellows-style pumps are well-known in the medical art, as disclosed by Marka. In particular, Marka discloses a

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multi-chambered bellows pump with one way inlet and outlet valves 3. The apparatus comprises a fixed bottom plate 12 and a movable top lever plate 7. Flexible chambers 1 comprise corrugated side walls 2, and are connected by one-way valves 4 such that upon movement of the lever lid 7, a vacuum is created in one chamber, causing fluid to flow into the other chamber (see FIG 1 and accompanying text). By rocking the lever back and forth, the operator pumps fluid through the device.

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the biological fluid correction system disclosed by Kutushov '479 into a single-housing pumping apparatus disclosed by Marka, since both structures are well-known in the art. One of ordinary skill in the art could have combined the elements disclosed by the cited prior art by known methods, and in that combination, each element would have performed the same function that it did separately. The only difference between the instant invention and the cited prior art is that the elements disclosed by Kutushov are assembled in a single bellows pump assembly as disclosed by Marka. The operation of the correction system disclosed by Kutushov is not dependent on the structure of the pumping apparatus, so the combination of the elements would work in the same manner as disclosed by the cited prior art.

Furthermore, it has been held that forming in one piece an element that was formerly constructed in multiple parts and put together does not patentably distinguish the combined element from the prior art. See MPEP § 2144.04(V)(B). In the instant case, it is the position of the Examiner that absent an objective showing of unexpected results, the claimed structure including the vessel for the ferreed sorbent and the mixing

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chamber in the same housing does not patentably distinguish from the disclosed ferreed sorbent vessel and mixing chamber in separate housings as disclosed by the prior art.

With regard to Applicant's simultaneous connection of the inlet to the vessel and the chamber, Applicant illustrates that this connection is made with two inlet hoses (see FIG 1). It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. It is the position of the Examiner that it would have been obvious to one having ordinary skill in the art at the time of invention to add a second inlet socket to the suggested combination.

With regard to claim 2, Marka illustrates that the lever lid 7 is in a single plane (see FIG 1).

With regard to claim 3, Marka illustrates that the attached lids over each chamber are deployed at a 180-degree angle to one another, comprising an "angle shape" as claimed by applicant.

With regard to claims 4 and 24, Marka illustrates that the two-chambered pumping apparatus comprises a generally rectangular shape with some rounded corners (see FIG 1).

With regard to claims 5 and 25, Marka discloses that plate 12 is stationary on the bottom of the apparatus.

With regard to claims 7 and 27, it is the position of the Examiner that the bottom of the pumping chamber suggested by the cited prior art is capable of being rotated in space by a user, meeting the limitations of the claim.

With regard to claims 8, 9, 13, 15, 21, 28, 32, 34, 36, and 37, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP § 2144.04(IV)(A). In the instant case, the applicant has not demonstrated any criticality to the claimed dimensions, and it is the position of the Examiner that the claimed dimensions would not affect the operation of the apparatus suggested by the prior art.

With regard to claims 10-12, 14, 29-31, and 33, Marka illustrates inlet and outlet valves 3, 4 located at various positions within the apparatus. It has been held that mere design changes to the placement of certain claimed elements are not patentable improvement over the prior art if the modification does not alter the operation of the device. See MPEP § 2144.04(IV)(C). In the instant case, the Applicant has not demonstrated any criticality to the claimed placement of the inlets and outlets. It is the position of the Examiner that the location of the inlet to the chamber does not affect the operation of the apparatus suggested by the prior art, and such a claim drawn to the location of the inlet does not patentably distinguish from the cited prior art.

With regard to claim 16, Kutushov '479 illustrates that magnets 72, 74, are installed outside, above and below the precipitation chamber (see FIG 2).

With regard to claim 35, Marka discloses that the top lid or lever 7 is rocked up and down, suggesting applicant's claimed driving gear application spot.

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3. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,980,479 to Kutushov in view of US 5,934,888 to Marka, further in view of US 4,750,868 to Lundback.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claim 22, the prior art fails to disclose that various parts of the apparatus are made of polyurethane. Lundback discloses a biological fluid pump with expandable chambers that may be formed of polyurethane (see column 3, lines 55-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the apparatus suggested by the cited prior art of polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 23, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP § 2144.04(IV)(A). In the instant case, the applicant has not demonstrated any criticality to the claimed dimensions, and it is the position of the Examiner that the claimed dimensions would not affect the operation of the apparatus suggested by the prior art.

Response to Arguments

4. Applicant's arguments filed 7 July 2008 have been fully considered but they are not persuasive.

5. Applicant argues that the instantly claimed invention is structurally distinct from the prior art, and reliance on the function of the suggested combination is an erroneous standard of obviousness. However, the Examiner is not relying solely on the function of the prior art apparatus in rejecting the claims as obvious. Rather, she is combining the structures of both the Kutushov and Marka devices wherein the three combined elements—ferreed sorbent vessel, mixing chamber, and pump—as part of the same housing perform the same functions as they did in separate housings. Accordingly, it is the notion that the function of the combined elements as disclosed by Kutushov in the housing suggested by Marka remains the same that renders the instantly claimed invention unpatentable over the prior art.

6. The declaration under 37 CFR 1.132 filed 22 October 2008 is insufficient to overcome the rejection of the pending claims based upon the cited prior art as set forth in the last Office action because: The cited prior art reasonably suggests all the claimed limitations.

7. First, the declaration refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Specifically, Applicant recites the advantages of the bellows pumping system, but does not address the advantages of combining the ferreed sorbent vessel with the mixing chamber in a common housing, which is an integral component of what Applicant's counsel contends is patentably distinguishable over the prior art. The declaration sets forth that the pumping action of the bellows allows for better mixing due to the flow stoppage, but is silent with regard to the common housing.

8. Second, the declaration does not provide sufficient evidence of unexpected results. Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. See MPEP §716.02. The Declarant has failed to provide any actual proof, in the form of clinical data, that the instantly claimed invention shows unexpected improvement over the prior art. It is well settled that unexpected results must be established by factual evidence. See MPEP §716.01(c). Due to the absence of tests comparing Applicant's claimed device with that of the closest prior art, it is the position of the Examiner that that the declarations assertions of unexpected results constitute mere argument.

9. Third, while the declaration provides the Declarant's opinion that the instantly claimed invention is more efficient and less traumatic for biological liquids, the Declarant's opinion is not given great deference. Since the Declarant is the inventor and Applicant, the Declarant is not a disinterested party. The Examiner is aware that an affidavit of an applicant as to the advantages of his or her claimed invention, while less persuasive than that of a disinterested person, cannot be disregarded for this reason

alone. See MPEP §716.01(c). However, the Declarant relies on conclusory statements that the results of the instantly claimed invention were unexpected without any supporting factual evidence. As such, Declarant/Applicant's opinion is of not of substantial evidentiary value.

10. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
23 October 2008